

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: DIGITEK® PRODUCT LIABILITY
LITIGATION

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

MEMORANDUM IN SUPPORT OF
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

In the three years since the recall of Digitek® tablets in the spring of 2008 that precipitated this litigation, no plaintiff has discovered or produced a double-thick Digitek® tablet. In fact, so elusive were double-thick tablets that Plaintiffs changed their theory mid-litigation, speculating that normal-sized but nevertheless defective tablets must somehow have been the source of their alleged injuries. But again, no Plaintiff has come forward with any scientifically reliable evidence that even one Digitek® tablet was out of specification because it contained too much or too little digoxin. Simply, Plaintiffs have no proof that defective Digitek® tablets—extra thick or not—ever reached the market, much less any one of the remaining Plaintiffs in this litigation.

Each plaintiff in a product liability case carries the burden to prove defect as an essential element of his or her case.¹ None of these Plaintiffs can. After three years of searching for the “smoking gun”—an out-of-specification tablet—discovery has run its course and all plaintiffs have to show for it is a collection of expert witnesses, all of whom concede that they have no

¹ This Court acknowledged proof of defect as the “key issue” in this litigation as recently as July 25, 2011, when it denied plaintiffs’ motion to set trial date and scheduling order in the McCornack case, No. 2:09-cv-00671. (See McCornack Doc. 116 at 6 (“Proving a manufacturing defect has been the key issue in this case, and every case in the MDL, since the beginning.”)).

direct evidence that Actavis marketed defective tablets,² and a smattering of Food and Drug Administration (“FDA”) documents containing allegations of regulatory violations by Actavis (a few related to Digitek®, most not).

Plaintiffs own experts concede that there is no direct evidence of defective Digitek®. But further, Plaintiffs lack even *circumstantial* evidence sufficient to prove defect. Specifically, the three types of indirect evidence upon which Plaintiffs rely—(1) allegations of general regulatory violations; (2) the 2008 Digitek® recall; and (3) evidence that some plaintiffs had higher-than-expected levels of digoxin in their blood—are insufficient because none of these can establish that Actavis manufactured and disseminated defective (meaning out-of-specification) Digitek®.

Because they cannot prove product defect with tangible or scientific evidence, Plaintiffs hope that generic allegations of regulatory violations contained in FDA documents persuade a jury that some sort of manufacturing defect must have existed in the recalled Digitek®. Their strategy amounts to no more than reliance on buzz words, like “recall” and “adulteration,” with absolutely no substantive evidence to prove that a single out-of-specification tablet ever left Actavis’s facilities and made its way into a consumer’s hands. Plaintiffs’ failure to carry their burden of proof calls for this Court to bring this protracted litigation to an end by granting summary judgment to Defendants.

STATEMENT OF UNDISPUTED FACTS

1. Mark Kenny, Plaintiffs’ purported expert in FDA regulations and compliance, admits that he can offer no opinion as to whether any consumer received an out-of-specification Digitek® tablet. When asked whether he has “any evidence at all that Digitek, outside its labeled specifications, reached consumers in this litigation,” Kenny conceded, “I have no evidence.”

² Defendants also challenge the admissibility of each of these “general liability” experts’ opinions. (*See* Defs’ Motion to Exclude, filed contemporaneously). But even if these experts may testify, none of their testimony establishes the essential defect element. (*See infra* at 8).

(Deposition of Mark Kenny (June 29, 2010), 134:10-19, attached to Defendants' General Background Statement ("Background Statement") as Exhibit 16).

2. Plaintiffs' expert Russell Somma, whose opinions focus on the technical aspects of Digitek[®] manufacturing, admits that he has seen no evidence that oversized tablets ever reached consumers. (See Deposition of Russell Somma (July 1, 2010), 157:25-158:4, attached to Background Statement as Exhibit 15). While he believes "there were still extra-thick tablets that [Actavis] did not detect," he agrees that he has "no actual basis for that other than [his] experience." (*Id.* at 209:18-21).

3. Plaintiffs' expert David Bliesner, another purported compliance expert, admitted during his deposition that he lacks any "direct proof" regarding the "recalled lots" of Digitek[®]. (Deposition of David Bliesner (Feb. 18, 2011), 443:17-23, attached to Background Statement as Exhibit 14). He testified that he has no evidence that adulterated—much less defective—tablets reached the market or consumers. (See *id.* at 443:9-16).

4. James Farley, also a professed regulatory expert, testified that he "wouldn't know if a patient in the market received a defective tablet unless [he] was told or saw data." (Deposition of James Farley (June 28, 2010), 35:18-24, attached to Background Statement as Exhibit 17). He has not seen any such data, and Mr. Farley's report never says that Digitek[®] was defective. In fact, when asked whether he would "tell a jury that Actavis was in fact producing defective Digitek," Farley responded, "I do not intend to tell anybody that because I don't know that." (*Id.* at 432:16-22).

5. None of Plaintiffs' experts included in their reports any observation or opinion that Actavis produced and released to market out-of-specification Digitek[®]. (See Defs' Mot. to Exclude Pls' General Liability Experts at 3).

6. In the three years since the 2008 Digitek[®] recall, no plaintiff (in an active or settled case) has ever produced a tablet that is outside its FDA-approved size specifications, nor any reliable testing evidence of a tablet that did not meet its FDA-approved content specifications. (*See* Background Statement at 6).

7. No plaintiff has identified an out-of-specification tablet in any of the Plaintiff's Fact Sheets ("PFS") or interrogatory responses in any of the remaining cases. (*See id.* at 6).

8. Actavis, using FDA-approved methods and sample sizes, tested each of the 152 recalled batches of Digitek[®]. All of the tablets tested met their FDA-approved specifications. (*See id.* at 9).

9. Between 2002 and 2008, the FDA collected and tested samples from at least 11 batches of Digitek[®]. All of these samples met specifications, including samples from seven batches (two in 2007, five in 2008) that were among the 152 recalled batches. (*See id.* at 10-11).

10. Independent laboratories tested 34 of the batches sent from Actavis to Mylan (Actavis's distributor) and UDL (a Mylan subsidiary). All of the batches were determined to be within specifications. Eleven of these 34 batches were recalled. (*See id.* at 11-12).

11. In 2007, Actavis hired Quantic Regulatory Services, an independent regulatory consultant, to audit its records regarding various drug products, including Digitek[®]. Quantic evaluated 39 Digitek[®] batches and concluded that manufacturing and laboratory records reliably confirmed the identity, strength, quality, and purity of Actavis's products. Nineteen of the 39 Digitek[®] batches Quantic audited were among those recalled. (*See id.* at 12-13).

LAW AND ARGUMENT

A. Plaintiffs' Burden is to Prove That Actavis Manufactured and Distributed Out-of-Specification Digitek[®] Tablets.

It is an essential requirement in every product liability case that the plaintiff prove that the product he or she received is defective. *See, e.g., Pro Serv. Auto., L.L.C. v. Lenan Corp.*, 469

F.3d 1210, 1214 (8th Cir. 2006) (“Proof that a plaintiff’s damages were caused by a defect in the product is an essential element of a plaintiff’s case under a product liability theory.”); *Severstal North Am., Inc. v. North Am. Refractories Co.*, No. 06-CV-10202, 2009 WL 1620015, at *5 (E.D. Mich. June 9, 2009) (“A manufacturing defect claim requires proof of ‘a defect attributable to the manufacturer. . . .’”); *Giddings v. Bristol-Myers Squibb Co.*, 192 F. Supp. 2d 421, 423 (D. Md. 2002) (identifying “the existence of a defect” as one of the prima facie elements that “[r]egardless of the recovery theory, the plaintiff in product liability litigation must satisfy.”).³

In a case that hinges on manufacturing defects (as this litigation does), proof of defect requires evidence that a plaintiff’s product was out of specification. *See, e.g., Singleton v. Int’l Harvester Co.*, 685 F.2d 112, 115 (4th Cir. 1981) (“In manufacturing defect cases, the plaintiff proves that the product is defective by simply showing that it does not conform to the manufacturer’s specifications.”); *Jones v. M&M Inflatables*, No. 2:07-cv-00425, 2010 WL 2159359, at *1 (S.D. W.Va. May 25, 2010) (Goodwin, J.) (“In manufacturing-defect cases, the plaintiff is claiming that a product is defective because it does not conform to the manufacturer’s specifications; that is, the product was not manufactured as designed.”). Where a plaintiff lacks such proof, summary judgment is appropriate. *See Mack v. Amerisourcebergen Drug Corp.*, No. RDB-08-688, 2009 WL 4342513, at *3 (D. Md. Nov. 24, 2009) (granting summary judgment because, though Plaintiffs made “great efforts” to prove causation, “they have made no showing with respect to the issue of defect.”).

³ “Defect” is an essential element of all of the plaintiffs’ product liability claims. *See, e.g., Johnson v. Dial Indus. Sales, Inc.*, No. 3:05-CV-47, 2007 WL 6036506, at *2 (N.D. W.Va. Sept. 21, 2007) (“To survive a motion for summary judgment, the plaintiff must make a showing that the [product] was defective under one of the applicable theories of liability including negligence, strict liability, or breach of warranty.”); *Miskin v. Baxter Healthcare Corp.*, 107 F. Supp. 2d 669, 670-71 (D. Md. 1999) (identifying “defect” as an essential element of plaintiffs’ product liability claims, which encompassed theories of “negligence, strict liability, fraud, failure to warn, intentional infliction of emotional distress, negligent infliction of emotional damages, and breach of implied warranty.”).

How a plaintiff may prove defect varies from jurisdiction to jurisdiction and may involve direct evidence that a specific defect existed in the plaintiff's product, expert testimony that the product used by plaintiff was out of specification, or circumstantial evidence that the product malfunctioned because of a defect. For example, in the non-pharmaceutical context, a plaintiff may have direct evidence of defect like measurements or photos related to a product's strength, size, or incorrect assembly. In other cases, where direct evidence is lacking, a plaintiff can establish his or her case by showing that injury occurred while using the product in its ordinary and intended manner, and that the event that caused the injury is of the type that would not normally occur absent a defect—the malfunction theory of defect. As one author described the inference arising from malfunction:

Under the Restatement Third, there is an inference that the plaintiff's harm was caused by a product defect, without proof of a specific defect, if the accident was of the type normally to be caused by a product defect and the accident was not solely the result of other causes. The plaintiff must eliminate potential causes for the accident other than the product defect.

Vicki Lawrence MacDougall, *The Impact of the Restatement (Third), Torts: Products Liability* (1998) on *Product Liability Law*, 62 Consumer Fin. L.Q. Rep. 105, 110 (2008). Sometimes the inference is easy. For example, if a step stool collapses under ordinary use, the jury may infer that it was not constructed as designed. In each case like this, the common thread is that a reasonable jury can arrive at a strong inference that the plaintiff would not have been harmed unless a product was not correctly made and resulted in direct harm to the plaintiff.

But prescription drugs are different. The concept of malfunction does not apply for several reasons. For one, harm does not mean malfunction in the prescription drug context. Consumers may experience idiosyncratic reactions to any medicine. See *In re Serzone Prods. Liab. Litig.*, 231 F.R.D. 221, 225-26 (S.D. W.Va. 2005) (“With drug-induced liver injury, however, a medication capable of causing severe liver damage in some people may cause no

liver harm at all in the vast majority of patients taking the drug.”). Moreover, adverse reactions can occur when a patient takes two or more drugs that interact with one another. (See Background Statement at 1-2). Adverse reactions will inevitably occur, too, in some percentage of patients even where the drug itself was pharmaceutically perfect and within all specifications. (See *id.*). Indeed, it has been noted that:

Although patients injured by medical devices may rely on a product malfunction approach, injuries associated with drug products rarely lend themselves to this sort of an analysis; **given the variability in patient response and the inevitability of unexpected adverse events, a seemingly inexplicable failure of a metabolized chemical hardly bespeaks some deviation from the manufacturer’s specifications.**

Lars Noah, *This is Your Products Liability Restatement on Drugs*, 74 Brook. L. Rev. 839, 841-42 (Spring 2009) (emphasis added).⁴ Consequently, a plaintiff cannot infer the existence of a pharmaceutical manufacturing defect from the fact that harm occurred. Instead, any plaintiff who intends to prove defect via circumstantial evidence must demonstrate why, precisely, the evidence they proffer reliably establishes that the drug was out-of-specification. Plaintiffs cannot satisfy that burden.

B. Plaintiffs Lack Any Direct Evidence That Defective Digitek® Tablets Reached the Market.

The record in this case is devoid of any evidence that a single out-of-specification Digitek® tablet—double-thick or not—reached the market, much less that it reached any of the

⁴ While Mr. Noah observes that “patients injured by medical devices may rely on a product malfunction approach,” numerous courts have held that the malfunction inference should not be allowed even in the device context—an area arguably *less* complex than the pharmaceutical context. See, e.g., *Webster v. Pacesetter, Inc.*, 259 F. Supp. 2d 27, 32 (D.D.C. 2003) (“[O]ne cannot presuppose the existence of a defect solely on the basis that unintended or undesirable results have occurred.”); *Koger v. Synthes N. Am, Inc.*, No. 3:07-CV-01158 (WWE), 2009 WL 5110780, at *3 (D. Conn. Dec. 17, 2009) (“[P]laintiff’s case requires complex medical and technical expert testimony to determine whether the breakage occurred as a result of a defect or a nonunion. . . . Thus, absent expert testimony, plaintiff cannot adduce sufficient proof of her claim to survive summary judgment.”).

remaining plaintiffs in this litigation. No plaintiff has ever produced physical or reliable scientific evidence of an out-of-specification tablet.⁵ (Statement of Undisputed Facts at ¶¶ 5-6) (“Undisputed Facts”). Plaintiffs’ remaining general liability experts all concede that they have no direct evidence that any defective Digitek[®] made it to market. (Undisputed Facts at ¶¶ 1-4; *see also* Mem. in Support of Defs’ Mot. to Exclude Pls’ General Liability Experts at 3). And in fact, all of the evidence uncovered by discovery suggests that the 20 double-thick tablets initially identified from batch 70924A were an aberration, were never released to the market, and that Actavis has consistently produced within-specification Digitek[®]. Actavis’s Digitek[®] manufacturing process was validated and, time and again, its batches tested within specifications. (Undisputed Facts at ¶¶ 7-8). This direct evidence of *non*-defective Digitek[®] is confirmed by the substantial affirmative product testing and record reviews conducted by the FDA, Mylan, UDL, and Quantic Regulatory Services. (*See* Undisputed Facts at ¶¶ 9-11).⁶

Plaintiffs simply lack direct evidence of defect. The balance of this brief addresses the means by which Plaintiffs attempt to prove defect via circumstantial evidence.

C. Violation of FDA Regulations Does Not Constitute Proof of Defect.

Unable to offer any “direct proof” of defective Digitek[®], Plaintiffs shift their efforts to proving defect circumstantially—an uphill battle, given that not even their experts can identify any reliable evidence that out-of-specification tablets existed. But undeterred, Plaintiffs have crafted a theory that relies on a series of FDA documents alleging general regulatory violations

⁵ Had the PSC or any MDL plaintiff found such a tablet, they would have produced it by now. In fact, Federal Rule of Civil Procedure 26 requires them to do so.

⁶ For their part, some Plaintiffs possess, but have refused to test (or reveal any testing of), an ample supply of unused Digitek[®] tablets. Accordingly, the tablets that have been tested by Actavis and third parties are the only “direct” testing evidence, and uniformly suggest that Actavis was not manufacturing and disseminating defective Digitek[®].

as evidence that Actavis produced “adulterated” Digitek®. This adulteration theory, however, cannot satisfy the proof-of-defect requirement because adulteration does not *mean* defective.

1. Proof of “adulteration” is not proof of “defect.”

“Adulteration” does not, and cannot, stand for proof of defect. Its meaning is limited by a statute, 21 U.S.C. § 351(a)(2)(B), which defines an adulterated drug to be one in which “the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice.” In other words, a drug is deemed adulterated if it was manufactured under conditions that violated any one of the FDA’s current Good Manufacturing Practices (“cGMP”) regulations, whether or not it actually fails to meet product specifications. These regulations—the primary way in which the FDA governs the manufacturing process—are process-related “prophylactic measures” designed “to prevent the distribution of poorly manufactured drugs and devices ‘by giving the Food and Drug Administration . . . additional authority to require that sound methods, facilities, and controls be used in all phases of drug manufacturing and distribution.’” *United States v. 789 Cases, More or Less, of Latex Surgeons’ Gloves*, 799 F. Supp. 1275, 1285 (D. P.R. 1992) (“[T]he cGMP regulations are intended to be preventive.”). Accordingly, cGMP violations lead only to “regulatory action,” *see* 21 C.F.R. § 210.1(b), and are not a basis for civil suits, *see, e.g., Howard v. Sulzer Orthopedics, Inc.*, No. 02–CV–0564–CVE–FHM, 2011 WL 2472594 at *6 (N.D. Okla. June 21, 2011) (“Based on the lack of a private cause of action in the FDCA, ‘many courts have held plaintiffs cannot seek to enforce it through negligence per se tort actions.’”) (citing *Bartlett v. Mut. Pharmaceutical Co., Inc.*, 731 F.Supp.2d 135, 154 (D.N.H.2010)).

Nothing in the adulteration statute states that an adulterated drug is either outside of United States Pharmacopeia specifications or defective under state tort law. *See* 21 U.S.C. §

351(a)(2)(B). Moreover, the FDA itself rejects attempts to equate adulteration with evidence of a manufacturing defect. The agency has repeatedly explained that adulteration means only “that the drug was not manufactured under conditions that comply with cGMP,” and “does not mean that there is necessarily something wrong with the drug.” Food and Drug Administration, “Facts About Current Good Manufacturing Practices (cGMPs),” <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm169105.htm> (last visited August 3, 2011).⁷

Federal courts, too, acknowledge that allegations of adulteration fall well short of proof of defect. *See, e.g., Krueger v. Johnson & Johnson Prof'l, Inc.*, No. 4:00-cv-10032, 2002 WL 34371190, at *5 (S.D. Iowa Sept. 10, 2002) (“[T]estimony [of failure to comply with FDA regulations] does not prove that the . . . device implanted in Krueger was defective, or that it was a proximate cause of his injuries.”); *Gellman v. United States*, 159 F.2d 881, 882 (8th Cir. 1947) (finding that an entire shipment of medical devices was “adulterated,” although “a much larger percentage of the shipment” was not defective). In fact, several courts have held that adulteration is not even a sufficient basis upon which to state a claim for a manufacturing defect. *See, e.g., Myers-Armstrong v. Actavis Totowa LLC*, No. C 08-04741 WHA, 2009 WL 1082026, at *4 (N.D. Cal. Apr. 22, 2009), *aff'd* No. 09-16055, 2010 WL 2232652 (9th Cir. June 3, 2010) (“That the [drug] was adulterated due to a lack of compliance with GMP requirements is not enough, without more, to state a claim.”); *In re Medtronic Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1157 (D. Minn. 2009) (cGMPs are “too generic, standing alone, to serve as the basis for plaintiffs’ manufacturing defect claims.”); *Ilarraza v. Medtronic*, 677 F. Supp. 2d 582, 588 (same).

⁷ Defendants have already requested that this Court take judicial notice of the FDA’s statement. (See Background Statement at 15).

2. **Allegations of adulteration are not circumstantial evidence of defect.**

Evidence that a drug is adulterated cannot support the inference that Plaintiffs seek, which is that an adulterated drug must somehow be flawed, dangerous, or defective. Courts have rejected that very inference because a drug may be “pharmaceutically perfect in content but still regarded as adulterated under the law.” *See, e.g., United States v. Lit Drug Co.*, 333 F. Supp. 990, 998 (D. N.J. 1971). And the FDA too rejects any assumption that an adulterated drug is out of specification or dangerous. When the FDA examines whether a product is adulterated, it does not ask whether the drug is harmful or meets content specifications. *See, e.g., United States v. Barr Labs., Inc.*, 812 F. Supp. 458, 486 (D. N.J. 1993) (explaining that the relevant inquiry to determine whether a drug is adulterated does not focus on the drug’s pharmaceutical content); *United States v. Bel-Mar Labs., Inc.*, 284 F. Supp. 875, 881-83 (E.D.N.Y. 1968) (a drug manufactured in violation of GMPs is adulterated, whether or not it is actually deficient).

Further, courts have cautioned against exporting regulatory conclusions like adulteration into civil tort cases for another reason—the differences between the burdens of proof. The FDA, as the agency charged with protecting public health, applies “a much lower [risk-utility] standard [of harm] than that which is demanded by a court of law.” *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1249-1250 (11th Cir. 2005). This lower standard favors overestimating risks as part of “the preventive perspective that the agenc[y] adopt[s] . . . to reduce public exposure to harmful substances.” *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001); *see also McClain*, 401 F.3d at 1249-50 (the FDA takes enforcement action “upon a lesser showing of harm to the public than the preponderance-of-the-evidence or the more-like[ly]-than-not standard used to assess tort liability.”). So when the FDA prevents a manufacturer from selling an adulterated product, it does so out of an abundance of caution, *not* because it has reason to believe the product contains a defect.

3. **Agency forms, reports, and letters criticizing Actavis's manufacturing processes are not proof that Digitek[®] tablets contained too much or too little digoxin.**

Just as adulteration is not proof of defect, neither are the regulatory documents that the FDA uses to communicate allegations of adulteration. In this litigation, Plaintiffs have asked their experts to review—and would present to a jury—documents including Form 483s, Establishment Inspection Reports, and Warning Letters. (See Background Statement at 16-17). But none of these documents are final agency action, and none say anything about the composition or content of any Digitek[®] tablets. At most, they are recordings of an FDA employee's belief that an Actavis manufacturing process violated a cGMP regulation—an observation that, for the reasons explained above, has nothing to do with whether Digitek[®] released to the market was defective.

Plaintiffs particularly emphasize Warning Letters issued by the FDA, lifting these agency allegations of adulterated product out of their regulatory context in an attempt to transform them into proof of defect. For example, Plaintiffs point to language from a February 2007 warning letter, which reported that because Actavis's quality control unit fell short of cGMPs, "there is no assurance that many drug products manufactured and released into interstate commerce by your firm have the identity, strength, quality and purity that they purport to possess." (See Feb. 1, 2007 Warning Letter at 1, attached to Background Statement as Exhibit 60). On its face, this letter says only that the FDA cannot *verify* that Actavis's products are of the quality, strength, and purity that they purport to be. Plaintiffs seek to recast this statement as an agency finding that Actavis's products are in fact *not* of the specified quality, strength, and purity, and therefore are defective. The warning letter, however, cannot support this theory. Nor can it shift the burden of proof onto Defendants to *disprove* the existence of defects. The letter itself acknowledges that Actavis's products may be within specification and "that to provide such

assurance, [Actavis] should promptly initiate an audit program by a third-party having appropriate cGMP expertise, to provide assurance that all marketed lots of drug products that remain within expiration have their appropriate identity, strength, quality, and purity.” (*Id.* at 6). Actavis did so, and Quantic Regulatory Services concluded that Actavis’s records reliably confirmed that its products were within specifications, including 19 batches of Digitek® that had been part of the recall. (*See* Undisputed Facts at ¶ 11).

D. Evidence of the 2008 Digitek® Recall Cannot Satisfy Plaintiffs’ Burden To Prove That Out-Of-Specification Digitek® Reached The Market.

Once the distraction of adulteration is filtered out, this litigation can be seen for what it has always been—a reaction to a high-profile drug recall. There are both factual and legal reasons why the 2008 recall cannot satisfy Plaintiffs’ burden of proof. Simply, recalls are preventative measures; they do *not* mean that the same problem that prompted the recall occurred in any specific consumer’s product. Thus, the fact that Actavis recalled Digitek® due to the possibility of double-thick tablets cannot prove that any particular plaintiff *received* an out-of-specification tablet. And here, the irrelevance of the recall is underscored by the fact that Plaintiffs have *abandoned* their double-thick theory—the basis of the recall—and now allege instead that they received normal-sized tablets with too much or too little digoxin—a theory that has nothing to do with the recall.

1. The recall of double-thick Digitek® tablets cannot support plaintiffs’ new defect theory.

Although the 2008 recall precipitated this litigation, Plaintiffs have finally abandoned any pretense that their claims are related to the double-thick tablets referred to in the FDA-approved recall notice. No Plaintiff in this litigation has ever produced a single double-thick tablet or reliable evidence that such a tablet made it to market. (Undisputed Facts at ¶¶ 5-6). Now, they label double-thick tablets as “merely a red herring,” (*See* MDL Doc. 147 at 1, 8; MDL Doc. 323

at 2; MDL Doc. 200-1 at 54), and focus on claims that any Digitek[®] tablet, even if properly sized, could hold “more than or less than the amount of active ingredient.” (MDL Doc. 200-1 at 54).

By abandoning the double-thick tablet theory, Plaintiffs march into new territory unsupported by the 2008 recall. Every statement made by the FDA about the Digitek[®] recall cautioned of the possibility of extra-thick tablets; no FDA document ever referred to normal-sized tablets with too much or too little digoxin. (*See* Background Statement at 3-6). By changing theories, Plaintiffs have thus drawn a bold line between the 2008 recall and their current claims, rendering the 2008 recall—once the heart of this litigation—irrelevant to any of their claims. For that reason alone, the 2008 recall cannot serve as a basis for inferring that any consumer received defective Digitek[®].

2. **A recall cannot prove that a specific Plaintiff received defective product, *especially* where the defect alleged is different from the reason for the recall.**

Recall evidence cannot prove the existence of a defect in an individual plaintiff’s product, even when the recall is about the very same defect that the plaintiff alleges. Here, it is each plaintiff’s obligation to prove that the alleged defect (out-of-specification tablets) existed in each individual case. *See, e.g., Bailey v. Monaco Coach Corp.*, 350 F. Supp. 2d 1036, 1045 (N.D. Ga. 2004) (“Bailey argues that a safety recall of the brakes constitutes direct evidence of the existence of a defect. However, ‘a manufacturer recall does not admit a defect in a particular product’”); *Perona v. Volkswagen of Am., Inc.*, 684 N.E.2d 859, 863 (Ill. Ct. App. 1997) (“A manufacturer recall does not admit a defect in a particular product, but refers to the possibility of a defect in a class of products.”); *Vockie v. Gen. Motors Corp., Chevrolet Div.*, 66 F.R.D. 57, 61-62 (E.D. Pa. 1975) (“The [recall] letter cannot be used to make the transition from the general to the particular and to prove that this particular 1965 Pontiac contained a defective

brake hose. The fact of a defective brake hose in this particular automobile at the time of this accident must be proved by direct evidence.”). The fact that a recall for the *possibility* of double-thick tablets occurred gets Plaintiffs nowhere. Even Plaintiffs’ experts admit that a product recall can occur where no true defect in the drug exists. (See Background Statement at 5).

Even if Plaintiffs had never changed their strategy and maintained that each plaintiff received double-thick tablets, the 2008 recall still could not satisfy their burden of proof. A recent decision from the Middle District of Pennsylvania is instructive and offers a compellingly similar set of facts. See *Dick v. Am. Home Prods. Corp.*, No. 1:05-cv-2384, 2009 WL 1542773 (M.D. Penn. June 2, 2009). In *Dick*, Wyeth, the manufacturer of a generic drug, voluntarily recalled one lot of drug capsules “after the company discovered that some capsules from the lot contained variable and unknown amounts” of an additional chemical. *Id.* at *1. The plaintiff sued after learning of this recall, alleging that her late husband consumed contaminated capsules that caused his death. *Id.* at *2. After noting the elements common to a products liability suit (namely, proof of defect and causation), the Court granted summary judgment to Wyeth. *Id.* at *3, 6. The court concluded that Plaintiff had:

[N]o evidence to support Plaintiff’s claim that Mr. Dick actually received or ingested any capsules that may have come from this lot. Even more fundamentally, there is no evidence to show that any etodolac capsules Mr. Dick did ingest—whether from Lot No. 9991052 or otherwise—actually contained any acebutolol, much less a quantity of acebutolol sufficient to cause him to suffer adverse health effects or cause his death.

Id. at *3. Here too, no Plaintiff has put forth *any* evidence that he or she received tablets that contained too much or too little digoxin, *much less* tablets of a sufficiently high or low dose to cause harm. Without that evidence, they cannot meet their burden of proof as a matter of law.⁸

⁸ *Dick v. American Homes* draws attention to yet another way in which Plaintiffs lack sufficient proof. Plaintiffs not only fail to prove that Actavis released defective Digitek[®] generally, but also fail to prove (even assuming that any tablets were defective) that any individual plaintiff received *enough* digoxin, a toxic dose, from the tablets to cause the harm that plaintiff alleged. See Federal Judicial Center, *Reference Manual on Scientific Evidence* 403, 419 (2d ed. 2000)

E. Test Results Showing Elevated Digoxin Blood Levels Cannot Satisfy Plaintiffs' Burden of Proof.

Unable to make this a case about regulatory adulteration or the 2008 recall, Plaintiffs are left with one last card to play—allegations that some plaintiffs were ill and that some tested positive for allegedly high levels of digoxin in their blood around the time of the Digitek® recall. This is the weakest of Plaintiffs' arguments and it too is legally incapable of satisfying Plaintiffs' burden of proof. None of this circumstantial evidence proves that Digitek® tablets contained erratic and uncontrolled amounts of digoxin, much less supports an inference that any individual's Digitek® contained a defect.

Essentially, Plaintiffs want to argue that purportedly elevated digoxin blood levels are evidence that each plaintiff must have received an out-of-specification Digitek® tablet. They are not. Where plaintiffs seek to infer a defect from the fact of a malfunction or injury, courts seek proof that the injury would not occur in the absence of a product defect. *See, e.g., Koch v. Sports Health Home Care Corp.*, 54 F.3d 773, at *5 (4th Cir. 1995) (table) (explaining that one may infer a product defect from an accident where it is “the type of accident that does not happen without a defect”); *Johnson v. Dial Indus. Sales, Inc.*, No. 3:05-CV-47, 2007 WL 6036506, at *2 (N.D. W.Va. Sept. 21, 2007) (“[T]he plaintiff offers no evidence eliminating other reasonable causes of the accident or proof that the accident could not happen without a defect present.

(explaining the need for plaintiffs to establish in a toxic tort case: 1) a toxic dose and 2) the duration of exposure). This failure of proof, common to all remaining cases, is an alternative ground on which this Court can grant summary judgment. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 263-64 (4th Cir. 1999) (“In order to carry the burden of proving a plaintiff's injury was caused by exposure to a specified substance, the ‘plaintiff must demonstrate the levels of exposure that are hazardous to human beings generally, as well as the plaintiff's actual level of exposure.’”); *see also Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194, 199 (5th Cir. 1996) (concluding that “[s]cientific knowledge of the harmful level of exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimal facts necessary to sustain the plaintiffs' burden in a toxic tort case.”).

Instead, the plaintiff simply offers self-serving, blind conclusions.”); *Carlton v. Goodyear Tire & Rubber Co.*, 413 F. Supp. 2d 583, 593 (M.D.N.C. 2005) (“The sixth and final factor . . . is that there is proof tending to establish that such an accident does not occur absent a defect This factor goes against plaintiff as well because plaintiff, defendant, and common sense agree that tires blow out for several reasons other than defects. . . .”).

Here, Plaintiffs may not infer the existence of a defective Digitek[®] tablet from the fact—if even proven—that a specific plaintiff’s blood contained an elevated digoxin level or that a plaintiff had some vague clinical signs and symptoms of digoxin toxicity. Digoxin toxicity may occur naturally even when the drug is administered at therapeutic dosages. (See Background Statement at 2). Even Plaintiffs’ experts admit this fact. (See *id.*). Elevated digoxin blood serum readings can result from a host of causes beyond too much digoxin, including renal failure, interactions with other drugs, acute illnesses, and electrolyte imbalances, among others. (See *id.*). There is, in short, proof that the injuries of which Plaintiffs complain commonly occur in the absence of a product defect. Consequently, too-high blood levels cannot satisfy Plaintiffs’ burden of proof.

CONCLUSION

Plaintiffs’ burden in a products liability suit is straightforward: they must prove that each plaintiff received, ingested, and was harmed by defective Digitek[®]. But these Plaintiffs lack any direct evidence. What circumstantial evidence they *do* have—regulatory criticism of Actavis’s adherence to cGMPs, a high-profile drug recall, and alleged injuries—cannot satisfy their burden of proof as a matter of law. For these reasons, this Court should end this protracted litigation by finding that Plaintiffs have failed to carry their burden of proving defect as a matter of law and by granting summary judgment on all remaining claims in MDL 1968.

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CERTIFICATE OF SERVICE

I hereby certify that on August 3, 2011, a copy of the foregoing **MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR SUMMARY JUDGMENT** was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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